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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,807	07/31/2000	Williams J. Louis	Q-59123	3573

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EXAMINER	
WRIGHT, SONYA N	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,807	LOUIS ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-52 and 54-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-52 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendments filed December 12, 2003 and February 6, 2004.

The objection to claims containing non-elected subject matter has been maintained. The rejection of claims 45-57 under 35 U.S.C. 112 has been maintained.

Claim Objections

Claims 45-57 are objected to for containing non-elected subject matter. It is suggested that Applicant limit the claims to the generic embodiment identified in the previous Office Action to overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CaAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of Invention

Claims 45-57 are directed to "the treatment of diseases of the central nervous system, cardiovascular diseases, glaucoma," and other diseases.

State of Prior Art

The prior art does not indicate which diseases the instant compounds are useful in treating.

Level of Ordinary Skill in the Art

It has not been shown in the specification that the testing protocol used is accepted in the art as being predictive of the alleged utility. The specification lacks enablement to support that the instant compounds could reasonably be expected to treat all cardiovascular system diseases, all kidney diseases, most all cardiovascular diseases, and all abnormal adrenal gland secretion disorders. There are a vast number of diseases, including diseases of the central nervous system and cardiovascular system, and glaucoma, and Applicant does not give support for treating all forms of these disorders. Therefore, the level of ordinary skill in the art is high.

Level of Predictability in the Art

The various forms of the diseases in claims 45-57 have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, the art pertaining to the diseases in claims 45-57 remains highly unpredictable.

Amount of Direction and Guidance Provided by the Inventor

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant gives limited guidance in pages 1-4 in their entirety; page 5, lines 1 and 2; and pages 15-30.

Existence of Working Examples

Applicant provides only 7 Examples, therefore, the specification does not support the full scope of the claims. In other words, Applicant does not support that the instant compound is useful in treating diseases of the central nervous system, cardiovascular diseases, glaucoma, " and other diseases as claimed in claims 45-57.

Breadth of Claims

The claims are extremely broad due to the vast number of diseases listed in claim 45.

Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

Response to Arguments

Applicant's arguments filed December 12, 2003 have been fully considered but they are not persuasive. Regarding the restriction requirement, Applicant argues that the generic embodiment developed by the Examiner does not encompass the compounds elected by Applicant in the response to restriction requirement filed on April 7, 2003. However, due to the vastness of the claimed subject matter, the examination could not proceed on the full scope of Applicant's invention set forth in the response filed April 7, 2003. The Examiner's generic embodiment is a subgenus of Applicant's invention set forth in the response filed April 7, 2003. Therefore, some subject matter, e.g. the examples Applicant provided in the response filed April 7, 2003, has been withdrawn from consideration. Subject matter which has been withdrawn from consideration in view of a restriction requirement may be pursued in divisional applications.

Regarding the rejection under 35 U.S.C. 112 first paragraph, Applicant argues that the prior art references listed in the response support the treatments recited in the present claims. Applicant argues that they have generated a body of experimental data and published data which supports the method of treatment claims in Table 1. Applicant provides further information in Tables 2 and 3 and in the references in the Appendix.

However, the prior art references provided give general information on methods of using similar compounds. The prior art references do not indicate that the instant compounds are useful for treating all forms of the diseases claimed. There are a plethora of diseases included in: diseases of the central nervous system, the cardiovascular system, the kidney, or diseases associated with abnormal adrenal gland secretions, hyperglycaemia, and peptic ulcer. Applicant has not shown support that the instant compounds are useful in treating all forms of the diseases as claimed.

Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 1 for treating any disease of the central nervous system, the cardiovascular system, the kidney, or diseases associated with abnormal adrenal gland secretions, hyperglycaemia, and peptic ulcer.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d

833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treating any disease of the central nervous system, the cardiovascular system, the kidney, or diseases associated with abnormal adrenal gland secretions, hyperglycaemia, and peptic ulcer by the compound of claim 1, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1. The art pertaining to a disease of the central nervous system, the cardiovascular system, the kidney, or diseases associated with abnormal adrenal gland secretions, hyperglycaemia, and peptic ulcer is highly unpredictable.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The experimental data provided in Applicant's response is limited and does not embrace the full scope of the claims. Applicants should limit the claims to methods of treating specific diseases which are supported by biological data.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (571) 272-0711. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The Official fax phone number for this Group is (703) 872-9306.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged

or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to Technology Center 1600 at (571) 272-1600.

for Joseph K. McKane
Supervisory Patent Examiner
Group 1600

Sonya Wright

April 28, 2004